

FEB 22 2007

U.S. Patent Appln. No.: 10/668,750  
Response to Office Action Dated August 25, 2006  
Page 2 of 9**REMARKS**

Claims 1-38 and 61 are pending. Claims 1-38 and 61 have been rejected. Claim 1 has been amended. No new matter has been added.

**Rejection under 35 U.S.C. §112, first paragraph**

Claims 1-38 and 61 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement because they allegedly contain subject matter that was not described in the specification in such a way as to convey to one skilled in that art that Applicants had possession of the claimed invention when the application was filed. The Examiner specifically stated that the claim amendment for an indicating means that indicates the degree of perfusion is indefinite because Applicants' specification does not disclose how the degree of perfusion is determined, only that blood flow is representative of the degree of perfusion. The Examiner also stated that "the claims recite determining the degree of perfusion when flow is substantially below normal and PCO<sub>2</sub> is substantially above normal and/or the pH is substantially below normal." The Examiner alleges that Applicants' specification does not teach determining the degree of perfusion when these conditions are met. Applicants traverse these rejections.

Applicants' specification, as originally filed, includes FIG. 3 showing "the tube 20 and sensor 22 are part of an instrument 24 that includes a flexible cable 26 that extends to a test instrument 30 that typically indicates the blood flow which provides an indicia of a degree of perfusion failure." See Applicants' Specification pg. 7, ¶ 73. Applicants' specification also discloses specific steps used to assess perfusion failure in a patient as follows

determine the expected range of measurements for subjects of similar age and health status as the patient as normal measurements of surface perfusion pressure and optical plethysmography may vary with the age of the subject. For a healthy patient, these two indices will be close to one. The blood flow in a mucosal tissue of the patient is determined. Next, the surface perfusion pressure and/or the optical plethysmography measurement is taken. Each of these values are compared with the expected value for a normal subject; patient values that are significantly lower than the normal values indicate perfusion failure. In addition, the rate-of-change of the patient's blood flow is measured over time with these

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three measurements. Rising values of blood flow, and an SPP index and an optical plethysmography index close to one indicate recovery, while declining values of blood flow and an SPP index and an optical plethysmography index less than one indicate a worsening of the patient's condition.

See Applicants' Specification pp. 8-9, ¶ 94.

Based on the foregoing, Applicants respectfully submit that the limitation to "said indicating means indicating the degree of systemic perfusion of the patient when the measured blood flow in the adjacent tissue is substantially lower than a normal measured blood flow and the measured PCO<sub>2</sub> is substantially higher than a normal measured PCO<sub>2</sub> . . ." is supported in the specification as originally filed in paragraphs 73 and 94, among other places. Reconsideration and allowance is respectfully requested.

#### **Rejection under 35 U.S.C. §112, first paragraph**

Claims 1-34 were rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter regarded as Applicants' invention. The Examiner specifically stated "in claim 1, the phrase 'the degree of systemic perfusion of the patient associated with' is awkward and it is unclear what the patient is associated with." Applicants have amended claim 1 to remove the word "associated" thereby obviating this rejection with respect to independent claim 1 and claims 2-32 depending therefrom. Because claim 33 is an independent claim that does not recite the word "associated" and claim 34 depends from claim 33, Applicants' believe the rejection of claims 33 and 34 should be withdrawn. Reconsideration and allowance is respectfully requested.

#### **CONCLUSION**

All rejections being addressed, it is believed that the claims are now in condition for allowance. Reconsideration and allowance are respectfully requested. If the Examiner believes that a teleconference would be of value in expediting the allowance of the pending claims, the undersigned can be reached at the telephone number listed below. It is believed that no additional fees are required. If for some reason it is determined that additional fees are required,

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the Commissioner is hereby authorized to charge any fees or overpayment to Deposit Account No. 50-1901 (Docket 11242-320).

Respectfully submitted,



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